Notice of Allowability	Application No.	Applicant(s)	
	10/055,509	CHANG ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1-31-06*.

2. ☒ The allowed claim(s) is/are *36-50*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 6-22-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ANISH GUPTA
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

Authorization for this examiner's amendment was given in a telephone interview with Thomas Webster on 8-7-06.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

On page 1 of the Specification, after the title "STABILIZED TERIPARATRIDE SOLUTION," the following has been added:

This Application is a continatuation of U.S. Serial Number 09/555,476, filed May 31, 2000, now U.S. Patent Number 6,770,623, which claims benefit of U.S. Provisional Application No. 60/069,075, filed Dec. 9, 1997.

In claim 36, has been amended as follows:

36. An aqueous pharmaceutical solution, which comprises: human parathyroid hormone (1-34) in a concentration of about 100-500 ug/ml; an acetate buffer to maintain the pH range of the solution from ~~greater than~~ 3 to 6; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures

thereof; a parenterally acceptable preservative; and water; wherein said solution is sterile and ready for parenteral administration to a human patient.

The following is an examiner's statement of reasons for allowance:

The claims are drawn to a pharmaceutical solution comprising human parathyroid hormone (1-34) in a concentration of about 100-500μg/ml, an acetate buffer to maintain the pH range of the solution from greater than 3 to less than 6; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol. glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution is sterile and ready for parenteral administration to a human patient.

The closest prior art of Bagnoli et al. (WO 94/08613) teach PTH (or a fragment thereof) in combination with stabilizers such as glycerin (see page 9-12). The reference states that for rectal pharmaceutical forms represented by a suppository or soft gelatin capsule, excepients such as polyalcohol and glycerin can be added (see page 6, lines 15-16). However, the prior art does not teach nor suggest the use of an acetate buffer, the pH range claimed, nor parenteral administration. All of the buffer utilized citrate buffers. In a previous office action, Holthuis was cited against the claims. It was indicated by Applicant that Holthius taught against the use of buffering agents such as acetic acid, since acetic acid was found to "volatize at differential rates during the freeze drying process, leading not only to a incosisting product but also to the loss of buffering agent, and hence inconsistent pH levels in the reconstituted product" (see US 5496801, col. 3, lines 48-58 and Col. 4, lines 3-8). Thus, there is not motivation to substitute the citrate buffer for the acetate buffer to arrived at claimed invention. Since the prior art does not suggest the use of acetate buffer and a pH between 3 and 6, the claimed invention is both novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

ANISH GUPTA
PRIMARY EXAMINER